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GAIN Report

Global Agricultural Information Network

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Nicaragua

Agricultural Biotechnology Annual Report

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Report Highlights:

In Nicaragua, the imports of Genetically Engineered crops (GE) are limited for the use of animal feeds since the Nicaraguan Commission of Risk Analysis of Living Modified Crops (CONARGEM) has not yet approved the use of GE crops for human consumption and/or cultivation. GE corn and soybean meal are the top import products. On the other hand, the lack of an operational biotech legal framework is a big limitation to promote the adoption of new biotechnologies.

Executive Summary:

Nicaragua is a signatory of the Cartagena protocol on biosafety and requires notifications for imports of Genetically Engineered crops (GE) and a risk analysis for biotech events.

At the moment, the imports of GE crops are limited for the use of animal feeds since the Nicaraguan Commission of Risk Analysis of Living Modified Crops (CONARGEM) has not yet approved the use of GE crops for human consumption and/or cultivation. GE corn and soybean meal are the top import products. In 2013, Nicaraguan imports of these two products reached over 113, 893 MT with a total value of US \$ 50 million. On the other hand, importers and/or exporters cannot request the approval of new GE events since the Nicaraguan biotech law, law 705, lacks the internal procedural norms (including the procedures to conduct a risk analysis for GE crops) required for its implementation. This is a big limitation to the adoption of new biotechnologies in Nicaragua. Some of the best prospects in the mid-term can be the approval of new GE corn and soybean events for animal feeds. However, the approval of new GE events will depend to a great extent on whether the procedural norms of law 705 are officially passed.

CHAPTER 1: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

PRODUCT DEVELOPMENT: Nicaragua has not developed any GE crops.

COMMERCIAL PRODUCTION: There is no commercial production of GE crops in Nicaragua.

EXPORTS: There is no commercial production of GE crops in Nicaragua and Nicaragua does not export GE crops to the United States or other countries.

IMPORTS: Nicaragua imports genetically engineered (GE) corn and GE soybean meal for the animal feed industry. In 2013, Nicaraguan yellow corn imports from the United States reached over 42,735 metric tons (MT) with a total value of US \$ 13.1million. Soybean meal imports reached over 71,158 MT with a total value of US \$ 37.5 million. Imports of other biotechnology products from other countries are limited or non-existent.

FOOD AID RECIPIENT COUNTRIES: Nicaragua continues to be a large food aid recipient due to its limited capacity to supply food for human and animal consumption. At present, the imports of GE crops for human consumption are not allowed since the Nicaraguan Commission of Risk Analysis of Living Modified Organisms (CONARGEM) has only approved the use of GE crops for animal feed purposes. Food aid products that are accepted are non-GE crops and

some GE processed food products, such as textured soy protein, soybean flour and refined vegetable oil.

PART B. POLICY:

REGULATORY FRAMEWORK: The two institutions that are responsible for regulating GE plants and animals are the new Institute of Agricultural Health and Protection (IPSA), recently created by the Government of Nicaragua, and the Ministry of Natural Resources and Environment (MARENA). Additionally, there are two commissions, the National Commission on Bio-safety (CONABIO) and the Commission of Risk Analysis of Living Modified Crops (CONARGEM), that serve as advisory bodies of the Government of Nicaragua (GON) on issues related to biosafety of GE crops and animals. Please refer below to see the specific roles of each institution.

Nicaragua subscribed to the Cartagena protocol in 2003. The same year, the GON began requiring notifications for imports of GE crops and the risk analysis for biotech events. However, no commission to perform risk analysis was formed until July 23, 2004, when the Commission of Risk Analysis of Living Modified Organisms (CONARGEM) was formed. CONARGEM is the Government of Nicaragua's (GON) advisory body on biosafety of GE crops and Animals.

On April 13, 2010, the GON published law 705 on the prevention of risks arising from organisms derived from new technologies through molecular biotechnology. This law supersedes chapter XVI of law 291 (basic law on animal and plant health) and establishes a complete comprehensive science based framework for the use of Genetically Engineered Organisms in confined use, research, release into the environment, commercialization (exports and imports), reproduction, multiplication, evaluation of field production, transportation, transit, bio-medication, conservation, and other uses. To date, law 705 has not been operational because it lacks the procedural norms for its implementation. This creates a big limitation to the Nicaraguan Biotechnology legal framework, as regulations cannot be implemented. Nicaraguan Importers currently rely on discretionary permits from the GON for the introduction of GE corn for animal feeds. . Please refer to the following link to see rule 705.

<http://legislacion.asamblea.gob.ni/SILEG/Gacetan.ssf/5eea6480fc3d3d90062576e300504635/23f47205d4aad71906257705006d686c?OpenDocument>

IPSA

The Institute of Agricultural Health and Protection (IPSA) will be the new competent authority for the implementation of the Nicaraguan biotechnology law (law 705 on the prevention of risks arising from living modified organisms through molecular biotechnology) in the fields of agriculture, forestry and aquaculture. In the past the Ministry of Agriculture and Forestry (MAGFOR) was the competent authority for the implementation of law 705. IPSA is the legal entity that supersedes the former General Direction of Animal and Plant Health Protection

(DGPSA) which was responsible for conducting the risk analysis of new GE crops. For more information about IPSA please visit the following link:

<http://legislacion.asamblea.gob.ni/normaweb.nsf/9e314815a08d4a6206257265005d21f9/8844f18c3ff68a0a06257cec0070c564?OpenDocument>

MAGFOR

The Ministry of Agriculture and Forestry's (MAGFOR) role on the Biotechnology framework is currently under review by the Government of Nicaragua due to the recent changes with IPSA.

MARENA

The Ministry of Environment and Natural Resources (MARENA) through the General Direction of Biodiversity and Natural resources is the competent authority for the implementation of law 705 on issues related to bioremediation, conservation, preservation and other uses related to biological diversity.

CONABIO

The National Commission on Bio-safety (CONABIO) has the main objective of harmonizing and recommending policies related to the use and implementation of bio-safety measures of GE crops. CONABIO also provides advice to the President of Nicaragua on issues related to biosafety. CONABIO is formed by the Ministry of Agriculture and Forestry (MAGFOR), the Ministry of Environment and Natural Resources (MARENA), Ministry of Trade, Ministry of Health, Secretary of the Nicaraguan Council of Science and Technology, an independent plant scientist, and four independent academics with experience in biosafety.

CONARGEM

The Commission of Risk Analysis of Living Modified Organisms (CONARGEM) is the advisory body on bio-safety to the Government of Nicaragua (GON), assigned to MAGFOR and MARENA on a rotational basis – Every six months CONARGEM's presidency pro-tempore changes between MAGFOR and MARENA.

Among CONARGEM's roles are: review requests related to the approval of new biotech events, propose guidelines for the risk analysis of GE crops, develop its procedural norms for operation, and assist the GON to formulate policies and strategies related to bio-safety.

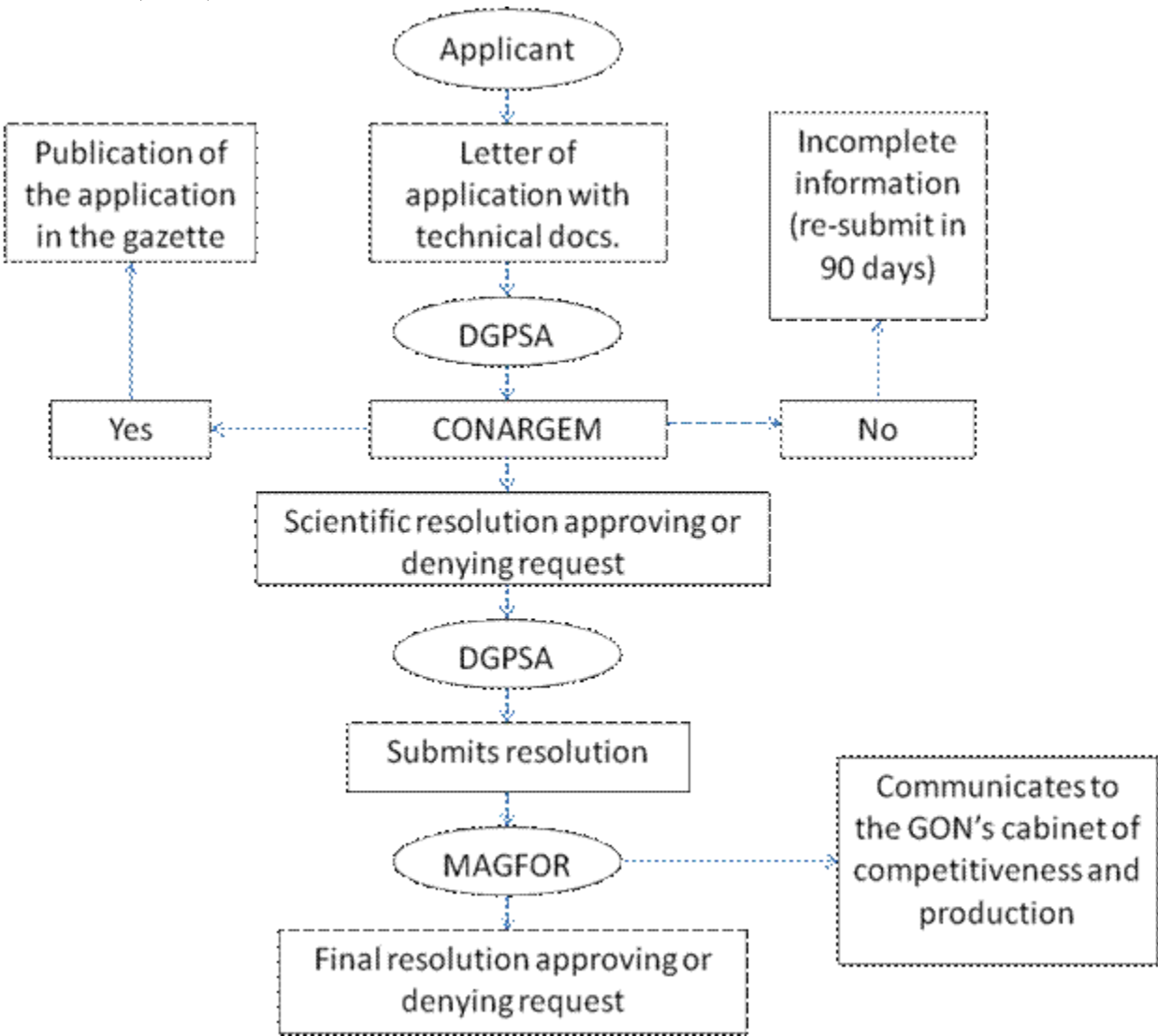
Note: The main difference between CONABIO and CONARGEM is that CONABIO is more of an advisory body of the President and CONARGEM, besides being an advisory body on

biosafety of MAGFOR and MARENA, is the commission responsible of analyzing requests related to the approval of new biotech events.

FLOW CHART OF THE APPROVAL PROCESS OF NEW GE EVENTS:

According to law 705, the regulatory treatment of the approval for GE food, feed, processing and environmental release is the same. The timeline usually followed for approval is of two hundred and seventy days counted from the day following on which the competent authority received the complete application.

Comment: At this time, importers and/or exporters cannot request the approval of new GE events since the Nicaraguan biotech law, law 705, lacks the internal procedural norms (including the procedures to conduct a risk analysis for GE crops) required for its implementation. The flow chart below is subject to changes since the Government of Nicaragua created the New Institute of Agricultural Health and Protection (IPSA).



Source: *Valoración de la situación actual de la bioseguridad en los aspectos normativos jurídicos y organizativos en Nicaragua.* José René Orue, 2009.

APPROVALS: At the moment, there are no GE corn events legally approved. In 2005, the Government of Nicaragua approved Ministerial resolution 034-2005 which approves the phyto-sanitary permits of 15 GE corn events (676, 678, and 680, MS3, MS6, BT 176, BT11, CT 1507, MON 863, MON 810, T14, T25, DLL25, and GA21). However, this ministerial resolution is no longer current. The private sector is trying to have the GON renew and update the aforementioned resolution.

FIELD TESTING: Up to now, CONARGEM has not approved any GE crop for cultivation and therefore field testing is not allowed.

STACKED EVENT APPROVALS: Law 705 does not make a difference in the approval process between plants that combine two or more approved traits and plants that have just one.

Stack event approvals follows the same procedures of any GE crop described in article II and III of law 705.

ADDITIONAL REQUIREMENTS: There are no additional requirements once the solicitation has been approved. For more information please refer to articles 17, 18, 19, 20, 21, 22, 23, 24 and 26 of law 705.

<http://legislacion.asamblea.gob.ni/SILEG/Gacetan.ssf/5eea6480fc3d3d90062576e300504635/23f47205d4aad71906257705006d686c?OpenDocument>

CO-EXISTENCE: As part of the risk assessment process for new biotech events stipulated on law 705, the competent authority, with the advice of the CONARGEM, may establish restricted areas for the release and use of living modified organisms. Therefore, policy measures related to the co-existent between GE and non GE crops will be considered case by case according to the results of the risk analysis.

LABELING: Nicaragua does not have a specific law for labeling on GE crops. However, according to law 705, GE exporters will need to comply with the provisions established on the Cartagena Protocol on Biodiversity and international and regional agreements on this matter. For the specific case of labeling seeds, exporters will need to comply with Nicaraguan Law 280 on production and trading of seeds which was approved on December 10, 1997 and published in the official Gazette on February 9, 1998. This regulation states that seed bags must have a label with information specifying its characteristics, genetic identification, germination, recommendations for management and conservation, quality and volume, etc. For more information please refer to the following link: <http://www.pgrfa.org/gpa/nic/textos/leyes/leydesemillas.pdf>

TRADE BARRIERS: U.S. GE corn and soybean meal have been entering the Nicaraguan market without major problems. However, Nicaragua has a major limitation within the legal framework to regulate GE crops as it was explained above. The principal law that regulates GE crops and animals (law 705) lacks the internal procedural norms for its implementation. This creates problems to importers who cannot request the approval of new GE crops because CONARGEM lacks the procedural norms of law 705 to evaluate the requests and take a decision. Another limitation is that the Ministerial Resolution

(034-2005) that approves the imports 15 GE corn events is no longer current and some previously approved events have been discontinued.

INTERLLECTUAL PROPERTY RIGHTS (IPRs): Nicaragua has a specific law (318) on Plant Variety Protection that establishes the standards to protect the rights of natural and legal persons that have created, discovered or developed a new plant variety either by natural means or genetic manipulation. Please refer to the link below for more information.

[http://legislacion.asamblea.gob.ni/Normaweb.nsf/\(\\$All\)/50E33B475568F720062570A100580157?OpenDocument](http://legislacion.asamblea.gob.ni/Normaweb.nsf/($All)/50E33B475568F720062570A100580157?OpenDocument)

CARTAGENA PROTOCOL RATIFICATION: Nicaragua is signatory of the Cartagena Protocol on biosafety to the convention on Biological Diversity. It also ratified this protocol on August 28, 2002 and entered into force in September 2003.

INTERNATIONAL TREATIES/FORA: Nicaragua is a member of several international organizations, including Codex Alimentarius, OIE, COP-MOP and IPPC.

RELATED ISSUES: Not applicable.

MONITORING AND TESTING: MAGFOR requires the testing for GE traces on every imported grain shipment. The tests are made by the Central American University Biotechnology Lab. Part of the purpose of the tests is to identify if the commodities imported have GE positive traces. For the specific case of corn, MAGFOR has a specific protocol that involves the custody of containers to make sure that corn seeds are not used for cultivation.

LOW LEVEL PRESENCE POLICY: Nicaragua does not have a low level presence policy of GE crops.

PART C: MARKETING

MARKET ACCEPTANCE AND PUBLIC/PRIVATE SECTOR OPINIONS:

Public awareness of GE emerging technologies among Nicaraguans is still limited. There are only three laboratories nationwide – the Central American University, the National Autonomous University and the Polytechnic University - which perform GE testing and research.

The Nicaraguan market is new to the concept of GE technologies. However, the private sector is interested in increasing the number of approved biotech events for corn and, in the future, to have GE crops approved for cultivation. The opposition to biotechnology comes mainly from some anti-GE NGOs which are very active in Nicaragua and promote initiatives that aims at rescuing, preserving and enhancing native seeds, while refusing entry of GE seeds into the country.

On the other hand, some Nicaraguan universities have started to include biotechnology in their curriculum, as they recognize the potential it has to contribute to food security, agricultural development and the environment. In 2013, the Vice President of Nicaragua, Omar Halleslevens, through the Nicaraguan Council of Science and Technology (CONICYT), and in conjunction with the National

Council of Universities (CNU) officially inaugurated a master's degree program in biotechnology. He mentioned that some of the primary objectives of this master's degree are to promote excellence in scientific research and technological development, train professionals in biotechnology and improve the Nicaraguan citizens' knowledge in this field to be able to develop biotechnology in its different applications. These types of steps from the Government of Nicaragua (GON) will help to increase awareness of the importance of biotechnology in the future. For more information on this master's degree please refer to the following link: <http://www.conicyt.gob.ni/index.php/component/content/article/3-noticiasrapidas/277-biotec>

MARKET STUDIES: Not applicable.

PART D: CAPACITY BUILDING AND OUTREACH

ACTIVITIES:

In October 2012, Embassy Managua's Economic and Foreign Agricultural Service Sections supported the 2012 Nicaraguan Agronomists Congress (Aug. 29 and 30), held at the IICA headquarters in Managua, using agricultural biotechnology outreach funds provided by the Department of State's Bureau of Economic and Business Affairs (EB). The Congress focused on climate change and the opportunities and challenges of the agriculture sector. The main message of the speakers was that the agriculture sector needs to look to innovative technologies to address the effects of climate change and the increasing demand of food. By 2050, food production must double to meet the needs of a growing world and countries like Nicaragua must take advantage of available technological advances. The biggest success of the Congress was that Biotechnology was positioned as a safe, environmentally friendly and powerful tool to help the agricultural sector adapt and mitigate the effects of climate change.

In May 2012, the United States Department of Agriculture (USDA) organized an international conference on Agriculture and Environment (CIAA), in Honduras. Ministers and Vice-Ministers of the Ministry of Agriculture and Forestry, from the eight member countries of the Central American Integration System (SICA), participated. As a concrete result of this conference, an Ad Hoc Technical Expert Group (AHTEG), comprised of regulators from SICA member countries, was formed. This group now intends to become a formal group of SICA, which can provide advice in biotechnology regulation, promotion of agriculture, and environmental conservation to the Central American region.

STRATEGIES AND NEEDS:

1. Nicaragua has a big limitation with the legal framework of law 705 since it lacks the procedural norms for its implementation.
2. Nicaragua does not have the institutional experience to implement biotechnology laws. There is a *critical need* for training of GON officials on the implementation of biotechnology laws.

CHAPTER 2: ANIMAL BIOTECHNOLOGY

PART E: PRODUCTION AND TRADE

BIOTECHNOLOGY PRODUCT DEVELOPMENT: There are no GE animals under development in Nicaragua at this time.

COMMERCIAL PRODUCTION: Nicaragua does not commercially produce any livestock clones or GE animals or products derived from animal biotechnologies.

BIOTECHNOLOGY EXPORTS: Nicaragua does not export any GE animals, livestock clones, or products from these animals at this time.

BIOTECHNOLOGY IMPORTS: Nicaragua has not imported GE animals or livestock clones or products from these animals.

PART F: POLICY

REGULATION: Law # 705 (on the prevention of risks arising from organisms derived from new technologies through molecular biotechnology) provides MAGFOR and MARENA with the legal authority to regulate animal biotechnology in Nicaragua. The following is the link to the text of the law:
<http://legislacion.asamblea.gob.ni/SILEG/Gacetas.nsf/5eea6480fc3d3d90062576e300504635/23f47205d4aad71906257705006d686c?OpenDocument>

LABELING AND TRACEABILITY: Labeling regulations have not been developed for products of animal biotechnology in Nicaragua.

TRADE BARRIERS: The principal law that regulates GE crops and animals (law 705) lacks the internal procedural norms for its implementation. Please refer to the section of trade barriers on the plant biotechnology chapter.

INTELLECTUAL PROPERTY RIGHTS (IPR): There is no IPR law for GE animals.

INTERNATIONAL TREATIES/FORA: Nicaragua participates in the World Organization for Animal Health (OIE), although Post is not aware of specific interventions by Nicaraguan officials on the subject of animal biotechnology.

PART G: MARKETING

MARKET ACCEPTANCE: The information provided above on the subject of acceptance of plant biotechnology generally applies to animal biotechnology. Post would expect the issue to be controversial if and when it becomes a public discussion topic.

PUBLIC/PRIVATE OPINIONS: Please see the section on plant biotechnology.

MARKET STUDIES: Not applicable.

PART H: CAPACITY BUILDING AND OUTREACH

ACTIVITIES: No activities have been developed by Post over the last years specifically on animal biotechnology.

STRATEGIES AND NEEDS: Please see plant biotechnology section on this subject